

**AVON-NCI “*Progress for Patients*” (PFP) Awards
For
Early Phase Clinical Interventions in Breast Cancer**

**Guidelines for Application, Review, and Award
(Updated 11/2004)**

Purpose:

These guidelines relate to the application for, and review of, administrative supplements to NCI-designated Cancer Centers for the conduct of innovative, early phase clinical interventions in breast cancer. This program was developed to provide a rapid means to support novel early phase clinical interventions aimed at the prevention, detection, diagnosis, or treatment of breast cancer. Projects considered to be responsive include the following:

1. Phase I or II or I/II treatment trials with any novel or previously approved agent.
2. Risk assessment or prevention studies involving humans.
3. Validation testing of a biomarker(s) in human subjects. This type of study can involve the use of specimens from either a retrospective or prospective trial.
4. Imaging studies in early detection, treatment monitoring, and response to therapy.

Projects that are still within the discovery phase or the pre-clinical development stage (e.g. involving toxicity screens on animals), or that focus on technology development, are *not* considered responsive. Additionally, funds from this program are not intended to create pilot or feasibility data for R01 or other applications. Questions regarding responsiveness of proposed projects to this initiative should be directed to the Program Director for your Cancer Center.

The inclusion of minorities or individuals from underserved populations as participants in the study and the involvement of a junior clinical investigator (Instructor, Assistant Professor, and Research Assistant Professor) in its design and execution are encouraged. Junior investigators are eligible to serve as Principal Investigators of PFP awards, with appropriate qualifications.

Eligibility:

All Cancer Center investigators are eligible to apply, so long as the above criteria in regard to project responsiveness are met.

Types and Number of Applications That May be Submitted:

A Cancer Center may submit:

1. One application involving a study that is exclusive to its own Cancer Center, or
2. One application involving a collaborative study with another Cancer Center, or
3. *Multiple applications, for example, one application which involves a study exclusive to its own Center and second application which is collaborative with another Cancer Center, or
4. *Multiple applications, all involving collaborative studies with other Cancer Centers

*More than two applications can be submitted as long as the total cost allowed (\$350,000 per institution) is not exceeded. For details, see section on Allowable Costs and Application Procedures, below

If a collaborative study between two Cancer Centers is being proposed, each Cancer Center must submit an independent application and budget request. If justified, collaborations with other institutions (and co-investigators) that do not have a Cancer Center Support Grant (CCSG) award may be proposed. In this case, the activities performed by an outside co-investigator(s) requiring financial support should be incorporated as a subcontract into the PFP application(s) submitted by the Cancer Center. See sections on Allowable Costs and Application Procedures, below.

Receipt Date:

The receipt date for applications is **March 1, 2005**.

Allowable Costs:

If one application is submitted, the request cannot exceed a maximum of \$250,000 in total costs (direct plus indirect) per participating Cancer Centers per year for a period of up to two years. If two applications (one institutional and one collaborative, or two collaborative) are submitted then the total costs for *both* applications cannot exceed \$350,000 per participating institution. The following table is provided to clarify the allowable costs for institutions submitting more than one application. The examples provided below are not all inclusive; additional budget scenarios are acceptable as long as they do not exceed the caps.

Examples of Project Budgets

<i>Collaborations</i>	Project #1	Project #2	Project #3	<i>Institution Total</i>
Institution A	\$250,000	\$100,000		\$350,000*
Institution B	\$100,000		\$150,000	\$250,000
Institution C		\$250,000	\$75,000	\$325,000
Institution D			\$100,000	\$100,000
<i>Project Total</i>	\$350,000	\$350,000	\$325,000	

* Institution A is at budgetary cap.

Collaborative projects involving more than two Cancer Centers should be discussed in advance with your Program Director.

Central coordination of submissions by the Cancer Center Director or his/her designee is essential, especially if the Cancer Center is submitting two applications. Budgets for each must be negotiated to ensure that total costs for both applications do not exceed \$350,000 and that funds are fairly appropriated to each proposed project.

Research or clinical activities performed outside of a Cancer Center can be included as subcontracts on a project but count towards the total cost cap for the parent institution. Funds may be used for any clinical or laboratory activity pertinent to the intervention with the exception of research involving animals. **Pre-clinical research on animals will not be supported.** In addition, it is not the intent of these awards to fund equipment or duplicate resources already available within a Cancer Center. As with the last round of applications, investigators should make maximum use of resources already available within their Cancer Center, especially with regard to clinical infrastructure. All applicable NIH policies must be followed.

Please note that costs to include the participation of underserved populations or minorities¹ in the study (e.g., travel expenses, patient navigators, case managers, or translators), if possible, are allowable and encouraged. Requests to support the partial salary and/or research activities of a junior clinical investigator are also encouraged.

Letter of Intent to Submit an Application:

To expedite the review process, you are requested to notify the Cancer Centers Branch of your intent to submit an application(s) for this administrative supplement, *using the attached template*. This notification should be provided either by e-mail (ncicenters-r@mail.nih.gov) or letter (at the address mentioned under Application Procedure) *by February 1, 2005*.

Application Procedures:

1. Cover Letter

A *cover letter* should accompany each application and be addressed to the Program Director for your Cancer Center Support Grant. The cover letter should request an “*Avon-NCI Progress for Patients*” (PFP) Award for the specific intervention proposed, provide the CCSG grant number, and be signed by the Cancer Center Director, the leader of the project, and the appropriate business official of the institution.

2. Where to Send the Cover Letter and Application:

The cover letter and five copies of each application should be sent to:

Cancer Centers Branch

¹ NOTE: “Special populations” include government-designated ethnic and racial groups, including American Indian or Alaska Native; Asian; African American; Hispanic or Latino; and Native Hawaiian or other Pacific Islander. The NCI’s working definition of “special populations” also includes medically underserved populations, such as rural, low-income, and low-literate individuals. These groups are generally characterized as experiencing higher cancer incidence and/or mortality rates or have inadequate access to, or reduced utilization of, high-quality cancer prevention, screening and early detection, treatment, and/or rehabilitation services.

Office of Centers, Training and Resources
National Cancer Institute
6116 Executive Blvd.
Suite 700, MSC 8345
Rockville, MD 20852 (if hand or express delivered)
Bethesda, MD 20892-8329 (if using US Postal Service)

Two copies of the entire application, including supporting documents (e.g., clinical protocol, patient consent forms) should also be submitted electronically to the Cancer Centers Branch on CD/Zip disks. (Note: No signatures are required on electronic files). The documents must be in MS Word format and PC compatible. A contact phone number and e-mail address must also be supplied for the project leader.

3. Format for the Application:

- Use the standard **face page** of the PHS 398 (09/04) form and follow instructions accordingly. For Item 2 check “yes” and provide the title “*Avon-NCI Progress for Patients*” Awards Program. In Items 7a through 8b, denote the direct and total costs for the first year, as well as for the entire period of support. Total costs should not exceed those stated under Allowable Costs above. The Cancer Center Director and the Business Official of the institution should sign the face page.
- Use the standard **budget pages** of the PHS 398 (09/04) application (form pages 4 and 5). Provide a budget justification for personnel, supplies, patient-associated costs, and other expenses. List any additional sources of support for the trial provided by the Cancer Center Support Grant, the Cancer Center, research grants, or other outside entities such as pharmaceutical companies.
- Provide **biographical sketches** of key personnel, using the standard PHS 398 (09/04) format.
- **In 10 pages or less, provide a summary** that includes the following:
 - Hypothesis to be tested
 - Significance and innovativeness of the intervention
 - Brief description of the research project that led to the proposed intervention
 - Documentation that patient population is available
 - A description and justification for the statistical design of the clinical study and ancillary laboratory studies
 - A description of available resources, including any clinical or laboratory facilities or data and protocol management systems relevant to the proposed intervention
 - A plan for gender and minority inclusion and accrual for research involving human subjects in accordance with NIH policy
 - If applicable, a plan for the support and mentorship of a junior clinical investigator

4. Additional Required Documentation. *Since it is the intent of this program to award funds for*

immediate use, applications will not be reviewed until all required materials are received.

- Complete clinical protocol and copies of informed consents
- Approval by the NCI Cancer Center's Protocol Review and Monitoring System (PRMS) or equivalent monitoring body
- A Data and Safety Monitoring Plan (DSMP). This may be the institutional DSMP approved by the NCI, with modifications appropriate to the study proposed. Applicants are encouraged to follow the recent NIH issuance on "Further Guidance on Data and Safety Monitoring for Phase I and Phase II Trials" located at <http://deainfo.nci.nih.gov/grantspolicies/datasafety.htm>.
- Additional guidance is available at: <http://www.cancer.gov/clinicaltrials/conducting/dsm-guidelines>.
- Availability of agent(s) being tested and verification of an existing IND held by the institution² or commercial source. NCI expects that the participating institutions or companies will assume the regulatory responsibility for any investigational drugs, biologicals, or devices that will be tested in a clinical setting. If using NCI sponsored agents, documentation of approval by the NCI Protocol Review Committee should be provided.
- Certification that all individuals involved in the design and conduct of the trial have completed education in the protection of human subjects in accordance with the NIH policy, "Required Education in the Protection of Human Research Participants", as announced in the June 5, 200 NIH Guide (revised August 25, 2000) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>). It is not necessary to submit certification for any individual for whom certification has already been provided on the parent grant.

Note: Hard copy and electronic copy of application should be in the following order:

- A.** Cover Letter (*include Cancer Center association, lead institution, participating institutions, title of project and total cost for 2 years*)
- B.** Face Page (*signed by Cancer Center PI and business official of the institution- for hard copy only*)
- C.** Abstract
- D.** Table of Contents
- E.** Budget-First Year
- F.** Budget-Entire Period
- G.** Budget Justification
- H.** Biographical Sketch of Principal Investigator
- I.** Biographical Sketches of Other Investigators (*in alphabetical order*)
- J.** Resources
- K.** [Response to Previous Critiques]-*for amended application*

- L.** Project Description
- M.** Checklist
- N.** Appendix(ices):
 - i.** Clinical Protocol
 - ii.** Patient Consent Form
 - iii.** IRB Approval(s)
 - iv.** Protocol Review and Monitoring System Approval(s)
 - v.** Data and Safety Monitoring Plans
 - vi.** Verification of IND (if applicable)
 - vii.** Protection of Human Research Participants – Certificates of Training
 - viii.** Letters of Collaboration
 - ix.** Manuscripts(s)
 - x.** Other Documents

5. Additional Material

Authorization to share materials pertaining to PFP applications with the Avon Foundation (*see enclosure*) should be included with the application. Note that an application may still be considered for an award even if no authorization form is submitted.

6. Inter-Cancer Center Collaborations

For Inter-Center collaborations, only the lead institution is required to submit a full application that details the overall goal of the study and project activities performed at its site. Participating institutions should submit a shorter application limited to a description of activities at their own specific sites. A clinical protocol should be submitted from the participating institution only if it differs from the submitted for the lead institution. All other materials that differ between the lead and participating institution(s) (e.g., budgets, IRB approvals, etc.) should also be submitted by the participating institution(s).

7. Amended Applications

Applications that were not funded in a previous cycle and have been amended for resubmission must address the criticisms in the prior critique. Please provide a 2-3 page document responding to the previous reviewers' critiques. This document should be placed before the project description in the application packet.

Review of the Application:

Applications will be reviewed by external clinical/translational (and basic, if applicable) researchers, a statistician, and a patient advocate using the following criteria:

1. Scientific merit
2. Innovation
3. Potential for significant impact on breast cancer
4. Feasibility for completion in two years or less

5. Adequacy of the plan for protection of human subjects
6. Adequacy of the plan to include minorities and underserved populations, to the extent possible within the applicable eligibility criteria
7. Inclusion of a plan to involve a junior clinical investigator(s)

The review process will be managed entirely through an Internet site. The merit of each application will ultimately be based on the critiques and scores provided by assigned reviewers; no panel assessments will be made. In the case of a dispute between assigned reviewers, an application will be reviewed by a select group of internal (NCI) or external reviewers.

Awards:

It is the intent to select meritorious applications for funding within 4-6 months of the application receipt date based on recommendations by the NCI.

Responsibilities:

This initiative is a partnership between the Avon Foundation and the National Cancer Institute. The NCI will be responsible for the application process (solicitation, receipt, responsiveness), review, administration of the awards, and a portion of the indirect costs associated with the awards. Avon will be responsible for supplying funds to the NCI for the direct costs and up to 10% of the indirect costs of the awards. The second year of funding will be contingent upon satisfactory progress.

LETTER OF INTENT (LOI) TO SUBMIT AN APPLICATION

Avon-NCI Progress for Patients (PFP) Awards Program

This format should be utilized when submitting a Letter of Intent for the *Avon-NCI PFP Awards Program*. The following information will assist the Cancer Centers Branch in the review of your application.

Title:

Description of Project:

(Should emphasize the human endpoint of the study. See Page 1 of Guidelines for this program. Basic research studies are not supported by this initiative.)

Project Leader(s):

Co-Investigators:

Institution(s)

Primary:

Secondary:

Specify Focus:

Targeted Gene _____

Biomarker

Profile

Other

Total Cost (per year) per Participating Cancer Center: _____

Time Frame for Study Completion: _____

Reviewer Expertise(s) Needed: _____

Authorization

The National Cancer Institute (NCI) and the Avon Foundation, Inc. have formed a partnership to provide for administrative supplements for early phase clinical interventions in breast cancer. The *Avon-NCI "Progress for Patients"* (PFP) awards program is sponsored by the Organ Systems and Cancer Center Branches of the NCI, with additional support provided by a \$20,000,000 gift from the Avon Foundation, Inc.

Subject to the authorization of the Applicant, NCI would like to share materials pertaining to PFP applications, including the applications and the reviewer's comments and evaluations, with the Avon Breast Cancer Crusade Advisory Board and the Avon Foundation, Inc. Board of Directors, pursuant to the terms of a confidentiality agreement. Such disclosure may be instrumental to NCI obtaining additional funds in the future. By signing below, Applicant further authorizes this disclosure.

A decision not to authorize the disclosures described above will *not* remove the Applicant's proposal from consideration for an award.

Applicant hereby acknowledges that the NCI and the Avon Foundation, Inc. shall not incur any liability merely for examining and transferring, to the extent authorized herein, any of the Grant-related documents.

Agreed and Accepted,

For the Applicant Organization

(Authorized Signatory for Grant Applicant)

Printed Name_____

Title_____

Institution_____

Address_____